

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

October 11, 2011

VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED
7010 3090 0002 2115 6340

Margaret Cherney
Bayer Cropscience LP
2 T. W. Alexander Drive
Research Triangle Park, NC 27709

RE: Offer to Cost Share

Dear Ms. Cherney:

Willowood Tebuconazole, LLC ('Willowood') currently holds a registration of a technical product containing tebuconazole as the active ingredient. As such, Willowood has recently received EDSP Test Orders for tebuconazole (Order / DCI # EDSP-128997-891). To the extent required by FIFRA §3(c)(2)(B) and FFDCA 408(p)(3) and (5), Willowood hereby offers to enter into an agreement to jointly develop or share in the cost of developing the following studies using tebuconazole as the test material:

- Endocrine Disruption Screening Program Assays:
 - o 890.1100 – Amphibian Metamorphosis (Frog)
 - o 890.1150 – Androgen Receptor Binding (Rat Prostate)
 - o 890.1200 – Aromatase (Human Recombinant)
 - o 890.1250 – Estrogen Receptor Binding
 - o 890.1300 – Estrogen Receptor Transcriptional Activation (Human Cell Line HeLa 9903)
 - o 890.1350 – Fish Short-Term Reproduction
 - o 890.1400 – Hershberger (Rat)
 - o 890.1450 – Female Pubertal (Rat)
 - o 890.1500 – Male Pubertal (Rat)
 - o 890.1550 – Steroidogenesis (Human Cell Line – H295R)
 - o 890.1600 – Uterotrophic (Rat)

In your return correspondence, please indicate the status of the above required studies. Alternatively, please provide an MRID number for any studies submitted to satisfy the above listed data requirements. Thank you for your cooperation.

Sincerely,


Janelle Kay
Agent for Willowood Tebuconazole, LLC

BCC: Tebuconazole Test Order Recipients:

Lanxess Corporation

ATTN: Stanley C. Oslosky
111 Ridc Park West Drive
Pittsburgh, PA 15275-1112

Luxembourg-Pamol, Inc.

ATTN: Michal Eldan, PhD
3647 Willowbend Blvd, Suite 810
Houston, TX 77054

Albaugh, Inc.

ATTN: Greg Mulhall
1525 N. E. 36th Street
Ankeny, IA 50021

Arysta Lifescience North America, LLC

ATTN: Dana E. Sargent
15401 Weston Parkway, Suite 150
Cary, NC 27513

United Phosphorus, Inc.

ATTN: Dave Olson
630 Freedom Business Center, Suite 402
King of Prussia, PA 19406

Irvita Plant Protection, NV

ATTN: Chuck Levey
4515 Falls of Neuse Rd., Suite 300
Raleigh, NC 27609

Punjab Chemicals and Crop Protection, Ltd.

ATTN: Rufus Bastian

10039 E. Troon North Drive

Scottsdale, AZ 85262

Rotam, Ltd.

ATTN: Frank E. Sobotka, PhD
4032 Crockers Lake Blvd., Suite 818
Sarasota, FL 34238

Source Dynamics, LLC

ATTN: Rufus Bastian
10039 E. Troon North Drive
Scottsdale, AZ 85262

Sharda Worldwide Exports Pvt, Ltd.

ATTN: Cheryl Wagner
7460 Lancaster Pike, Suite 9
Hockessin, DE19707-0640

Amtide, LLC

ATTN: Der-I Wang
21 Hubble
Irvine, CA 92618

Trustchem Co., Ltd.

89 Hagzhang Road, D2, 23rd Floor
Nanjing, PRC 210019

[Also :

Repar Corp.

P. O. Box 4321
Silver Spring, MD 20914]

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Margaret Cherney
Bayer Bioscience LP
2 T. W. Alexander Drive
Research Triangle Park, NC 27709

COMPLETE THIS SECTION ON DELIVERY

A. Signature

X E. Bullock

☐ Agent☐ Addressee

B. Received by (Printed Name)

E. Bullock

C. Date of Delivery

10/17/11

- D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type

- ☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee)

☐ Yes

2. Article Number

(Transfer from service label)

7010 3090 0002 2115 6340



RE: Willowood Tebuconazole LLC - EDSP DCI

Janelle Kay

to:

Wilhelmena Livingston

10/27/2011 11:04 PM

Cc:

Leanne Pruett

Hide Details

From: Janelle Kay <Janelle@PyxisRC.com>

To: Wilhelmena Livingston/DC/USEPA/US@EPA,

Cc: Leanne Pruett <Leanne@PyxisRC.com>

History: This message has been replied to and forwarded.

Dear Wilhelmena,

Thanks for your follow-up note. I spoke with Leanne of our offices and below is a history of correspondence:

- On August 5, 2011, Willowood requested information to join the EDSP cost sharing agreement from Bayer (Bayer is leading the cost-sharing and is solely responsible for developing the data).
- On Sept. 16, 2011, Bayer refused to provide Willowood with a copy of the EDSP cost sharing agreement in order to allow Willowood to join the consortia.
- On Oct. 11, 2011, Willowood provided Bayer (and other tebuconazole registrants) with an irrevocable 3 (c)(2)(B) offer to jointly develop the EDSP data. We had hoped that with this offer, Bayer would provide us with the agreement, but it has not.

Based on our previous conversations with OGC, we understand that the 3(c)(2)(B) offer is sufficient to satisfy EDSP test order requirements. Leanne can send you a certification to offer to jointly develop shortly. Since I will be traveling out of the country, I would ask that you contact Leanne in case you have any questions.

Regards,

Janelle

Janelle Kay

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4110 136th St. NW

Gig Harbor, WA 98332

E: Janelle@PyxisRC.com

T: 1-253-853-7369

F: 1-253-853-5516

-----Original Message-----

From: Livingston.Wilhelmena@epamail.epa.gov [<mailto:Livingston.Wilhelmena@epamail.epa.gov>]

Sent: Tuesday, October 18, 2011 7:54 AM

To: Janelle Kay

Subject: RE: Willowood Tebuconazole LLC - EDSP DCI

Dear Ms. Kay,

This is a follow-up message with regards to Willowood Tebuconazole LLC, confirming that they entered into an agreement with the consortia to develop the EDSP data requirements for tebuconazole. Please respond to this message. If you have any questions regarding this matter please let me know.

Sincerely,

Wilhelmena Livingston, Chemical Review Manager USEPA Office of Pesticide Programs Pesticide Re-evaluation
Division Risk Management and Implementation Branch IV
(703) 308-8025

Dear Ms. Kay,

As per our conversation today with regards to Willowood Tebuconazole LLC, entering into an agreement with Bayer CropScience to develop the EDSP data requirements for tebuconazole. Willowood Tebuconazole LLC, had 60 days from their initial response (August 11, 2011) to make an offer to pay to join the consortia. The due date for the offer is October 11, 2011. Please confirm that the agreement is in place with the consortia.

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10/27/2011 11:04 PM

Cc:

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RE: Willowood Tebuconazole LLC - EDSP DCI
Janelle Kay to: Wilhelmena Livingston
Cc: Leanne Pruett

10/31/2011 05:21 PM

From: Janelle Kay <Janelle@PyxisRC.com>
To: Wilhelmena Livingston/DC/USEPA/US@EPA,
Cc: Leanne Pruett <Leanne@PyxisRC.com>

Wilhelmena,

The problem is that Bayer has refused to provide us with the cost sharing agreement. Willowood provided a cost-sharing offer and Leanne sent you the certification for that offer.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
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-----Original Message-----

From: Livingston.Wilhelmena@epamail.epa.gov [mailto:Livingston.Wilhelmena@epamail.epa.gov]
Sent: Monday, October 31, 2011 6:07 AM
To: Janelle Kay
Subject: RE: Willowood Tebuconazole LLC - EDSP DCI

Dear Ms. Kay,

Please respond to this message with an electronic copy of Willowood Tebuconazole LLC, EDSP Cost Sharing Agreement that was sent to Bayer to allow you to join the consortia. If you have any questions, please let me know.

Sincerely,

Wilhelmena Livingston, Chemical Review Manager USEPA
Office of Pesticide Programs Pesticide Re-evaluation
Division Risk Management and Implementation Branch IV
(703) 308-8025

From: Janelle Kay <Janelle@PyxisRC.com>
To: Wilhelmena Livingston/DC/USEPA/US@EPA
Cc: Leanne Pruett <Leanne@PyxisRC.com>
Date: 10/27/2011 11:04 PM

Subject: RE: Willowood Tebuconazole LLC -
EDSP DCI

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(703) 308-8025



Re: Fw: Willowood Tebuconazole LLC - EDSP DCI 
Mark Dyner to: Wilhelmena Livingston
Cc: Jane-Scott Smith, Laurel Celeste

12/05/2011 02:25 PM

Wilhelmena,



Mark Dyner
EPA Office of General Counsel

Wilhelmena Livingston

Hi Mark,


12/02/2011 09:26:42 AM

From: Wilhelmena Livingston/DC/USEPA/US
To: Mark Dyner/DC/USEPA/US@EPA
Cc: Jane-Scott Smith/DC/USEPA/US@EPA
Date: 12/02/2011 09:26 AM
Subject: Fw: Willowood Tebuconazole LLC - EDSP DCI

Hi Mark,



Wilhelmena Livingston, Chemical Review Manager
USEPA Office of Pesticide Programs
Pesticide Re-evaluation Division
Risk Management and Implementation Branch IV
(703) 308-8025



Privileged attorney-client communication

----- Forwarded by Wilhelmena Livingston/DC/USEPA/US on 12/02/2011 08:55 AM -----

From: Janelle Kay <Janelle@PyxisRC.com>
To: Wilhelmena Livingston/DC/USEPA/US@EPA
Cc: Leanne Pruett <Leanne@PyxisRC.com>
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